

## Ethical Questions on the Use of Magnetic Field Reports

Results from National Toxicology Program draft reports on carcinogenesis and promotion of 60-Hz magnetic fields (1,2) are a mixed bag of apparent effects in some cases and no effects in other cases. The studies were carried out, apparently, with the intent to provide information that can be used in making health policy for humans. I contend that these studies cannot be used for this purpose because of two implicit assumptions that were made when the studies were being designed.

First, it was assumed that the relevant magnetic field parameter for inducing biological effects is a pure 60-Hz sine-wave, and such was used. But the public is exposed to something very different, as the authors admit (1):

While power line magnetic field exposures are predominantly sine-wave fields, residential and occupational exposures may include square waves, sawtooth waves, and other wave forms. Harmonics (120 Hz, 180 Hz, etc.) may also be found. Further, as appliances are switched on and off, spikes or transients in fields may occur. It is not feasible to evaluate all possible variables in large animal studies. Therefore, this study used linearly polarized, pure sine-wave exposures at 60 Hz, with the fields turned on when the sine wave was at zero amplitude and gradually increased over seven to nine cycles (between 0.11 and 0.15 seconds) to full intensity, and similarly gradually decreased to avoid transients. The NIEHS studies evaluate the predominant component (60-Hz sine-wave magnetic fields) without all the complexities of the exposures that occur in residential and occupational settings.

Biological theory, as well as substantial published data, indicates that the field characteristics which people are actually exposed to, and which the authors eliminated from their experiments, are the effective agents (3). Thus, if one wants to use the results of these studies in setting health policy for people exposed to power line fields, one must first prove that a pure sine-wave field is the relevant parameter for inducing biological effects.

The second implicit assumption made by the authors was that magnetic fields are an alien substance, such as arsenic, etc. Thus, they set up the experiments using a toxicology model—in a dose-response format. In fact, electrical and magnetic fields are not alien substances; rather, they are fundamental in the functioning of living organisms. I have addressed this matter in detail in several publications (3,4). Thus, if one wants to use the results of these studies in setting health policy for people exposed to power line fields, one must first prove that a toxicology model is appropriate.

Although the technology in these experiments may be fine, it would not be ethical to use the results in the formulation of health policy for the human population without

first proving that the implicit assumptions that were made are true. These comments also apply to other recent studies, such as the study by Mandeville et al. (5).

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## REFERENCES AND NOTES

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4. Frey AH. Is a toxicology model appropriate as a guide for biological research with electromagnetic fields? *J Bioelectr* 9 (2):233–234 (1990).
5. Mandeville R, Franco E, Sidrac-Ghali S, Paris-Nadon L, Rocheleau N, Mercier G, Désy M, Gaboury L. Evaluation of the potential carcinogenicity of 60 Hz linear sinusoidal continuous-wave magnetic fields in Fischer F344 rats. *FASEB J* 11:1127–1136 (1997).

## Response: Magnetic Field Reports

The logic of Allan Frey's first criticism ("First, it was assumed that the relevant magnetic field parameter for inducing biological effects....") is unclear. By citing remarks of the authors (1), he is acknowledging that the predominant component of environmental fields is the 60-Hz component (60 Hz in the United States and 50 Hz in Europe), yet he is being critical of its use as the candidate exposure parameter in the toxicology and carcinogenesis studies, which is puzzling. His reasons for dismissing the 60-Hz component as the active agent are "Biological theory as well as substantial published data...." indicate that other attributes of the magnetic field are the "effective agent," and he cites a reference of his own (2) in support of his position. Apparently Frey has not read the breakout group report from the first RAPID Program Science Review Symposium on theoretical mechanisms and *in vitro* findings (3), which considered mechanism theories for EMF biological effects. The report (3), reflecting the views of experts in 1997, indicates that the biological effects that have been reported in the literature are "not expected based on known biophysical mechanisms." Therefore, it is not clear what "biological theory" Frey is referring to. Frey suggests that "properly tuned" magnetic fields should be used for exposure purposes (4). The main magnetic fields of interest have been those of power frequencies; however, in the EMF

RAPID program, other magnetic field frequencies are being considered.

In regard to the "substantial published data" that supports Allan Frey's first criticism, he has failed to note that there has been no independent replication of the biological effects reported in the archival literature. The four EMF Regional Exposure Facilities (at the Food and Drug Administration in Rockville, MD; the National Institute for Occupational Safety and Health (NIOSH) in Cincinnati, OH; the Oak Ridge National Laboratories in Oak Ridge, TN; and the Pacific Northwest Laboratories, in Richland, WA) supported by the EMF RAPID program and the Department of Energy (DOE), where all studies are done in a blind fashion including sham/sham controls, have failed to replicate a single *in vitro* effect after 3 years of effort. Only recently have there been reports of replication of an *in vitro* study (conducted elsewhere and yet to be published). The failure in the United States (5) to replicate the cancer promotion results that were first observed in Germany using "pure sine-wave" power frequency magnetic fields is a recent example in which the replication effort was unsuccessful. Because the original promotion study employed pure sine-wave magnetic fields and reported adverse biological effects, the same purely sinusoidal fields had to be used in the replication effort. Why Frey is critical of the use of sine-wave fields in the promotion replication study is unclear.

Frey's view that "one must first prove that a pure sine-wave field is the relevant parameter for inducing biological effects" is better directed at the other candidate exposure parameters. For example, transients (spikes) in the magnetic field have been suggested as a candidate exposure parameter. In 1991, when the protocols for the toxicology study were being developed, there were no published data or theory regarding transients. It was not until September 1994 at the DOE/NIOSH workshop on EMF exposure assessment that fast transients were suggested as a candidate exposure parameter. In considering other candidate exposure parameters, the NIEHS, through the EMF RAPID program, supported an evaluation of the third and fifth harmonic, transients, and intermittent field exposures in rats using pineal and serum nocturnal melatonin levels, pineal serotonin *N*-acetyltransferase activity, and ornithine decarboxylase levels in various tissues as parameters of a biological effect. These studies have been completed and the results were presented at the third Science Review Symposia, held in Phoenix, Arizona 5–9 April 1998.

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